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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/913,811	09/24/97	SUGIHARA	H 356972020100

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HM11/0705

EXAMINER
BASKAR, P

ART UNIT	PAPER NUMBER
	1645

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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# Office Action Summary

Application No.  
08/913,811

Applicant(s)  
SUGIHARA HIROKAZU

Examiner  
Padma Baskar

Art Unit  
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 5, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 12, 14, and 16 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 14, and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 24
- 18) ☒ Interview Summary (PTO-413) Paper No(s) 24, 26, 27
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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### **DETAILED ACTION**

**Upon further consideration, the final rejection as set forth in the previous office action is hereby withdrawn**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Thomas Wheelock on 5/3/01.

The application has been amended as follows:

Claims 1-11 have been canceled.

2. Applicant's amendment filed on 4/5/01 is acknowledged. Claim 12 has been amended. Claims 13 and 15 have been canceled. Claims 12, 14 and 16 have been amended. Claims 12, 14 and 16 are pending in the application.

3. The terminal disclaimer filed on 4/5/01 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent 5,563,067 has been reviewed and is accepted (obviates the double patenting rejection of record)

4. Applicant's supplementary IDS filed on 5/15/01 is acknowledged and a signed copy is attached with this office action.

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5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 12, 14 and 16 are rejected as being vague and indefinite for the recitation of "chronic effect". What are the metes and bounds of chronic effect? As claimed it is impossible to determine the metes and bounds of the claimed invention.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Parce et al 1994 (5,278,048)

Parce et al disclose a method of testing cell affecting agents (i.e., chemical substances) on living cells (i.e., neural or muscle tissue contains living cell; examiner is viewing a collection of similar cells as tissue). This method also discloses testing drugs on cells by measuring the pH by using semiconductor electrode (see claims). It is inherent that this method uses at least two electrodes (i.e., plurality of electrodes), -ve electrode and + electrode to measure the changes in pH (see claims 1-17). The prior art anticipated the claimed invention. In the absence of evidence to the contrary the disclosed prior art method would read on the claimed method. Since the Office does not have the facilities for examining and comparing applicants' method with the method of the prior art, the burden is on applicant to show a novel or unobvious

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difference between the claimed method and the method of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

8. Claims 12, 14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Giaever et al, 1993, (U.S. Patent 5,187,096).

Giaever et al describes a method which comprises a detector for detecting electrical properties of endothelial cells, fibroblasts (examiner is viewing a collection of similar cells as tissue ) when chemical substance thrombin is exposed to the cultures. (See column 3, lines 22-67). The invention has several applications including testing the drugs. The prior art anticipates the claimed invention. In the absence of evidence to the contrary the disclosed prior art method would read on the claimed method. Since the Office does not have the facilities for examining and comparing applicants's method with the method of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed method and the method of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

9. Claims 12-14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nisch et al (Biosense.Bioelect 1994, 9:737-741).

Claims are directed to a method of testing the effect of medicine t chronic effect on neural or muscle tissue.

Nisch et al describes a method which comprises a detector for detecting electrical properties of neuronal activity in vitro (page 738-739). He measures a detectable electrical signal before and after stimulation in figure 7 which is observed (i.e visible property). He further

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describes a testing device comprising electrical measurement portion (i.e visible) visible detection portion (Figure 3-monitor, figure 4, figure 5, figure 6 etc).

Nisch et al does not teach that the method used for tissues. However, Stedman's Medical Dictionary defines tissue as "a collection of similar cells and the intercellular substances surrounding them . There are four basic tissues in the body: 1) epithelium; 2) the connective tissue, including blood, bone, and cartilage; 3) muscle tissue; and 4) nerve tissue. In addition, while the specification puts forth preferred embodiments, the specification does not define or restrict the term tissue to a particular embodiment. Therefore , based on Stedman's Medical Dictionary the term tissue encompasses blood , which are single cells floating.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the Nisch et al method with a reasonable expectation of success because use of this method and device for tissue culture system are readily available. An artisan of ordinary skills would have been motivated to modify the prior art method for measuring the electrical properties of tissues before and after the addition of medicine or drugs because it would have helped in determining the toxicity of the drug on tissue as taught by Nisch et al.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar Ph.D. whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 A.M. to 4:00 P.M. EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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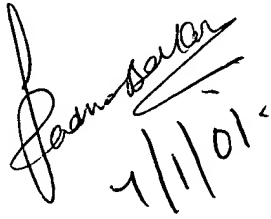
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

6/6/01

Handwritten signature of Padma Baskar and the date 7/1/01.